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*Practice limited to Federal Agencies



March 10, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

WRITER'S DIRECT NUMBER:
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Art Unit 1651

Re: U.S. Utility Patent Application
Appl. No. 10/694,189; Filed: October 28, 2003
For: **Defined Systems for Epithelial Cell Culture and Use Thereof**
Inventors: Judd *et al.*
Our Ref: 0942.4180003/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (10 sheets citing 58 documents);
3. A copy of document **AR10** cited on Form PTO-1449; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

RWE/FRC/lam
Enclosures

234754.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Judd *et al.*

Appl. No. 10/694,189

Filed: October 28, 2003

For: **Defined Systems for Epithelial
Cell Culture and Use Thereof**

Confirmation No. 2747

Art Unit: 1651

Examiner: *To be assigned*

Atty. Docket: 0942.4180003/RWE/FRC



Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The Examiner's attention is directed to the following co-pending U.S. Patent Application, which is directed to related technical subject matter: U.S. Patent Application No. 09/028,514, Gorfien *et al.*, filed February 23, 1998 and submitted herewith as document **AR10**. A copy of this document is included.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Copies of all other documents were previously cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/695,926, Judd *et al.*, filed October 26, 2000, which is relied upon for

an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

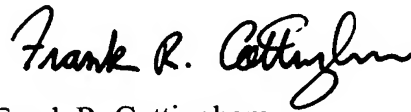
It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Judd *et al.*
Appl. No. 10/694,189

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

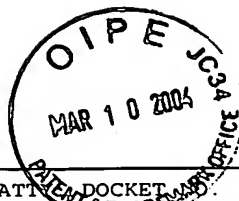
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, reading "Frank R. Cottingham". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: MAR. 10, 2004
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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTENTION DOCKET MANAGER
0942.1 TRADEMARKS/RWE/FRCAPPLICATION NO.
10/694,189APPLICANT
Judd et al.FILING DATE
October 28, 2003GROUP
1651

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	4,533,637	08/06/1985	Yamane et al.	435	240	05/18/1982
	AB1	4,673,649	06/16/1987	Boyce et al.	435	240	07/15/1983
	AC1	4,743,679	05/10/1988	Cohen et al.	530	350	02/24/1986
	AD1	4,767,704	08/30/1988	Cleveland et al.	435	68	10/07/1983
	AE1	4,940,666	07/10/1990	Boyce et al.	435	240.2	12/09/1986
	AF1	5,122,469	06/16/1992	Mather et al.	435	240.2	10/03/1990
	AG1	5,189,148	02/23/1993	Akiyama et al.	530	399	07/03/1990
	AH1	5,292,655	03/08/1994	Wille, Jr.	435	240.3	01/29/1990
	AI1	5,316,938	05/31/1994	Keen et al.	435	240.31	12/18/1992
	AJ1	5,342,777	08/30/1994	Cole et al.	435	240.31	03/03/1992
	AK1	5,364,785	11/15/1994	Mather et al.	435	240.2	05/11/1993

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	WO 90/08771	08/09/1990	PCT			Yes No
	AM1	EP 0 408 146 A2	01/16/1991	Europe			Yes No
	AN1	WO 92/05246	04/02/1992	PCT			Yes No
	AO1	EP 0 481 791 A2	04/22/1992	Europe			Yes No
	AP1	EP 0 531 733 A1	03/17/1993	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Boyce, S.T., and Ham, R.G., "Calcium-Regulated Differentiation of Normal Human Epidermal Keratinocytes in Chemically Defined Clonal Culture and Serum-Free Serial Culture," <i>J. Invest. Dermatol.</i> 81:33s-40s, The Williams and Wilkins Co. (1983)
	AS	<u>1</u>	Chaproniere-Rickenberg, D.M., and Webber, M.M., "Zinc Levels in Zinc-Stabilized Insulin are Inhibitory to the Growth of Cells In Vitro," <i>In Vitro</i> 19(5):373-375, Tissue Culture Association (1983)
	AT	<u>1</u>	Daley, J.P., et al., "Growth of Human Epidermal Keratinocytes in Keratinocyte Serum-Free Medium," <i>Focus</i> 12(3):68-71, Life Technologies, Inc. (1990)

EXAMINER

DATE CONSIDERED

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4180003/RWE/FRC	APPLICATION NO. 10/694,189
	APPLICANT Judd et al.	
	FILING DATE October 28, 2003	GROUP 1651

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,378,612	01/03/1995	Nakashima et al.	435	69.6	12/28/1992
	AB2	5,395,756	03/07/1995	Igarashi	435	69.4	04/04/1994
	AC2	5,443,968	08/22/1995	Takazawa et al.	435	70.3	01/03/1994
	AD2	5,461,030	10/24/1995	Lindenbaum	544	4	11/29/1993
	AE2	5,474,931	12/12/1995	DiSorbo et al.	435	240.31	09/21/1993
	AF2	5,573,957	11/12/1996	Cardone et al.	436	518	09/28/1994
	AG2	5,576,194	11/19/1996	Chan	435	69.6	10/01/1993
	AH2	5,631,159	05/20/1997	Marshall et al.	435	383	09/22/1993
	AI2	5,633,162	05/27/1997	Keen et al.	435	384	03/04/1994
	AJ2	5,641,647	06/24/1997	Fischer et al.	435	69.1	08/24/1993
	AK2	6,103,529	08/15/2000	Price et al.	435	404	10/10/1997

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 95/01434	01/12/1995	PCT			Yes No
	AM2	WO 97/34999	09/25/1997	PCT			Yes No
	AN2	WO 98/24883	06/11/1998	PCT			Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Ethier, S.P., et al., "Influence of Hormone and Growth Factor Interactions on the Proliferative Potential of Normal Rat Mammary Epithelial Cells In Vitro," <i>J. Cell. Physiol.</i> 132:161-167, Alan R. Liss, Inc. (1987)
	AS	2	Gilchrest, B.A., et al., "Characterization and Partial Purification of Keratinocyte Growth Factor From the Hypothalamus," <i>J. Cell. Physiol.</i> 120:377-383, Alan R. Liss, Inc. (1984)
	AT	2	Gilchrest, B.A., et al., "Attachment and Growth of Human Keratinocytes in a Serum-Free Environment," <i>J. Cell. Physiol.</i> 112:197-206, Alan R. Liss, Inc. (1982)

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FOREIGN PATENT DOCUMENTS							
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>3</u>	Gill, D.M., "Mechanism of Action of Cholera Toxin," in <i>Advances in Cyclic Nucleotides Research</i> , Vol. 8, P. Greengard and G.A. Robinson, eds., New York, Raven Press, pp. 85-118 (1977)
	AS	<u>3</u>	Gospodarowicz, D., and Cheng, J., "Heparin Protects Basic and Acidic FGF From Inactivation," <i>J. Cell. Physiol.</i> 128:475-484, Alan R. Liss, Inc. (1986)
	AT	<u>3</u>	Green, W.N., et al., "cAMP stimulation of acetylcholine receptor expression is mediated through posttranslational mechanisms," <i>Proc. Natl. Acad. Sci. USA</i> 88:854-858, National Academy of Sciences of the USA (1991)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>4</u>	Hahm, H.A., and Ip, M.M., "Primary Culture of Normal Rat Mammary Epithelial Cells Within a Basement Membrane Matrix. I. Regulation of Proliferation by Hormones and Growth Factors," <i>In Vitro Cell. Dev. Biol.</i> 26:791-802, Tissue Culture Association (1990)	
AS	<u>4</u>	Hahm, H.A., et al., "Primary Culture of Normal Rat Mammary Epithelial Cells Within a Basement Membrane Matrix. II. Functional Differentiation Under Serum-Free Conditions," <i>In Vitro Cell. Dev. Biol.</i> 26:803-814, Tissue Culture Association (1990)	
AT	<u>4</u>	Ham, R.G., "Formulation of Basal Nutrient Media," in <i>Methods for Preparation of Media, Supplements, and Substrata for Serum-Free Animal Cell Culture</i> , Barnes, D.W., et al., eds., New York, Alan R. Liss, Inc., pp. 3-21 (1984)	

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>5</u>	Imagawa, W., et al., "Keratinocyte Growth Factor and Acidic Fibroblast Growth Factor Are Mitogens for Primary Cultures of Mammary Epithelium," <i>Biochem. Biophys. Res. Commun.</i> 204:1165-1169, Academic Press, Inc. (1994)
	AS	<u>5</u>	Lambert, K.J., and Birch, J.R., "Cell Growth Media," in <i>Animal Cell Biotechnology</i> , Vol. 1, Spier, R.E., and Griffiths, J.B., eds., New York, Academic Press, Inc., pp. 85-122 (1985)
	AT	<u>5</u>	Marcelo, C.L., et al., "Stratification, Specialization, and Proliferation of Primary Keratinocyte Cultures," <i>J. Cell. Biol.</i> 79:356-370, The Rockefeller University Press (1978)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Pirisi, L., et al., "Transformation of Human Fibroblasts and Keratinocytes with Human Papillomavirus Type 16 DNA," <i>J. Virol.</i> 61:1061-1066, American Society for Microbiology (1987)
	AS	<u>6</u>	Pittelkow, M.R., and Scott, R.E., "New Techniques for the In Vitro Culture of Human Skin Keratinocytes and Perspectives on Their Use for Grafting of Patients With Extensive Burns," <i>Mayo Clin. Proc.</i> 61:771-777, Mayo Foundation for Medical Education and Research (1986)
	AT	<u>6</u>	Pittelkow, M.R., and Shipley, G.D., "Serum-Free Culture of Normal Human Melanocytes: Growth Kinetics and Growth Factor Requirements," <i>J. Cell. Physiol.</i> 140:565-576, Alan R. Liss, Inc. (1989)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>7</u>	Price, F.M., et al., "A New Culture Medium for Human Skin Epithelial Cells," In Vitro 16:147-158, Tissue Culture Association (1980)
	AS	<u>7</u>	Rheinwald, J.G., and Green, H., "Serial Cultivation of Strains of Human Epidermal Keratinocytes: the Formation of Keratinizing Colonies from Single Cells," Cell 6:331-344, MIT Press (1975)
	AT	<u>7</u>	Shipley, G.D., and Pittelkow, M.R., "Control of Growth and Differentiation In Vitro of Human Keratinocytes Cultured in Serum-free Medium," Arch. Dermatol. 123:1541a-1544a, American Medical Association (1987)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>8</u>	Shipley, G.D., et al., "Growth of Normal Keratinocytes and Fibroblasts in Serum-Free Medium Is Stimulated by Acidic and Basic Fibroblast Growth Factor," <i>J. Cell. Physiol.</i> 138:511-518, Alan R. Liss, Inc. (1989)
	AS	<u>8</u>	Turner, T., et al., "Serum-Free Culture of Enriched Mouse Anterior and Ventral Prostatic Epithelial Cells in Collagen Gel," <i>In Vitro Cell. Dev. Biol.</i> 26:722-730, Tissue Culture Association (1990)
	AT	<u>8</u>	Watson, C.A., et al., "Variability Among Human Umbilical Vein Endothelial Cultures," <i>Science</i> 268:447-448, American Association for the Advancement of Science (April 1995)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Waymouth, C., "Preparation and Use of Serum-Free Culture Media," in <i>Methods for Preparation of Media, Supplements, and Substrata for Serum-Free Animal Cell Culture</i> , Barnes, D.W., et al., eds., New York, Alan R. Liss, Inc., pp.23-68 (1984)
	AS	<u>2</u>	Wille, J.J., Jr., et al., "Integrated Control of Growth and Differentiation of Normal Human Prokeratinocytes Cultured in Serum-Free Medium: Clonal Analyses, Growth Kinetics, and Cell Cycle Studies," <i>J. Cell. Physiol.</i> 121:31-44, Alan R. Liss, Inc. (1984)
	AT	<u>2</u>	Willey, J.C., et al., "Relationship of Ornithine Decarboxylase Activity and cAMP Metabolism to Proliferation of Normal Human Bronchial Epithelial Cells," <i>J. Cell. Physiol.</i> 124:207-212, Alan R. Liss, Inc. (1985)

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0942.4180003/RWE/FRC	APPLICATION NO. 10/694,189
	APPLICANT Judd et al.	
	FILING DATE October 28, 2003	GROUP 1651

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>10</u>	U.S. Patent Application No. 09/028,514, Gorfien et al., filed February 23, 1998 (NOT PUBLISHED)
	AS	<u>10</u>	
	AT	<u>10</u>	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	